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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/823,433

04/12/2004

Dario Alessi

4-20682D

5032

1095

7590

09/05/2006

EXAMINER

RUSSEL, JEFFREY E

NOVARTIS

CORPORATE INTELLECTUAL PROPERTY

ONE HEALTH PLAZA 104/3

EAST HANOVER, NJ 07936-1080

ART UNIT

PAPER NUMBER

1654

DATE MAILED: 09/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/823,433	ALESSI ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Jeffrey E. Russel	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 July 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) 9-18, 20-30, 32, 33 and 35-44 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 34 is/are allowed.
- 6) ☒ Claim(s) 1-8, 19 and 31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09/091,763; 09/091,109; 09/068,702.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>20041214</u> . | 6) <input type="checkbox"/> Other: _____  |

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1. Claims 9-18, 20-30, 33, and 35-44 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on July 12, 2006.

Claim 32 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on July 14, 2006.

Applicant's election of the invention of Group I and the species RAC-PK and its analogs and isoforms, in the reply filed on July 12, 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. The Sequence Listing filed April 12, 2004 is approved.

3. The disclosure is objected to because of the following informalities: There is no Brief Description of the Drawings as is required by 37 CFR 1.74. The sentence bridging pages 1 and 2 of the specification appears to be comprised of portions of the immediately preceding and immediately following sentences. It is believed that the sentence bridging pages 1 and 2 should be deleted. At page 30, line 25, "the" should be changed to "then". At page 43, second-to-last line, "IGF-1" is misspelled. SEQ ID NOS need to be inserted after the amino acid sequences recited at page 58, last line, and page 59, line 4, and in the tables on pages 69-71 of the specification. See 37 CFR 1.821(d). Appropriate correction is required.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re Colianni*, 195 USPQ 150 (CCPA 1977) and have been adopted by the Board of Patent Appeals and Interferences in *Ex parte Forman*, 230 USPQ 546 (BPAI 1986). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. With respect to (1), the nature of Applicants' elected invention is the treatment of diseases, including diabetes and cancer, by administering RAC-PK, its analogues, and its isoforms. The invention also includes pharmaceutical compositions comprising RAC-PK, its analogues, and its isoforms. With respect to (2), the prior art of record does not teach that RAC-PK, its analogues, or its isoforms, can be administered therapeutically to treat any disease. The prior art does not disclose the ability to administer protein kinases in vivo so that they can target and enter a cell membrane and function within a signal pathway. With respect to (3), the relative skill of those in the art is high. With respect to (4), the pharmaceutical arts in general are relatively unpredictable. With respect to (5), the claims are relatively broad, embracing the treatment of all diseases related to glycogen metabolism and/or protein synthesis, and embracing the use of any and all RAC-PK analogues and isoforms. With respect to (6), at page 15, lines 13-14, Applicants teach away

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from the use of proteinaceous compounds (which would include RAC-PK) as therapeutic agents, stating that they are mainly useful for research. At page 17, last full paragraph, Applicants indicate that RAC-PK inhibition is useful in treating cancer. However, the claims embrace treating cancer by administering RAC-PK. The specification does not explain how the provision of additional RAC-PK to cells would result in the inhibition of RAC-PK which Applicants indicate is useful in treating cancer. The specification does not provide any guidance as to how RAC-PK, its analogues, or its isoforms can be administered therapeutically so that the active agents will target and enter an appropriate cell membrane and function within an appropriate signal pathway. With respect to (7), there are no working examples in which RAC-PK, its analogues, or its isoforms are used to treat a disease. The only disclosed examples in which RAC-PK is administered to a cell are at page 35, first full paragraph, and the paragraph bridging pages 35 and 36. However, the specification and the prior art of record do not indicate that activity in a myotube assay is predictive of in vivo success. With respect to (8), given the relatively undeveloped state of the prior art, the lack of direction and guidance provided by Applicants' specification, and the absence of any working examples in which RAC-PK, its analogues, or its isoforms are administered in vivo or to treat a disease, the quantity of experimentation necessary to be able to practice the invention would be vast. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-3, 6-8, 19, and 31 are rejected under 35 U.S.C. 102(e) as being anticipated by Skyler et al (U.S. Patent No. 5,422,125). Skyler et al teach treating diabetes by administration of vanadate, optionally in combination with insulin. See, e.g., the Abstract and claims 1, 2, and 13. Vanadate is inherently an activator of RAC-PK. Insulin inherently is an agent capable of influencing the activity of RAC-PK by phosphorylation. In view of the similarity in structure and methods of use between the active agents of Skyler et al and Applicants' claimed and disclosed active agents, inherently RAC-PK will be modified by phosphorylation at one or both of amino acids 308 and 473 by phosphorylation in the method of Skyler et al to the same extent claimed by Applicants. Sufficient evidence of similarity is deemed to be present between the method of Skyler et al and Applicants' claimed method to shift the burden to Applicants to provide evidence that the claimed invention is unobviously different than that of Skyler et al. Note that a prior art reference need not recognize or suggest Applicants' intended results in order to anticipate Applicants' claimed method on the basis of inherency. See *Ex parte Novitski*, 26 USPQ2d 1389, 1391 (POBA 1993); *In re Cruciferous Sprout Litigation*, 64 USPQ2d 1202 (CAFC 2002); and more generally MPEP 2112. With respect to instant claim 31, process limitations do not impart patentability to product-by-process claims where the product is otherwise anticipated by or obvious over the prior art.

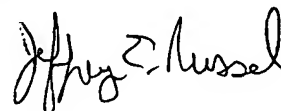
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7. Claim 8 is rejected under 35 U.S.C. 102(b) as being anticipated by the Konishi et al article (Biochem. Biophys. Res. Comm., Vol. 205, pages 817-825). The Konishi et al article teaches recombinantly expressed and purified RAC-PK  $\alpha$  and  $\beta$ . See, e.g., the Abstract and page 819, last full paragraph. With respect to the claim limitation "pharmaceutical", an intended use limitation does not impart patentability to product claims where the product is otherwise anticipated by the prior art.

8. Claim 34 is allowed. The prior art of record does not teach a RAC-PK polypeptide comprising at least one of the two specified mutations. While the Alessi et al article (EMBO J. Vol. 15, pages 6541-6551) teaches such polypeptides, the Alessi et al article is not prior art against claim 34 because claim 34 is entitled under 35 U.S.C. 120 to the benefit of the filing date of, e.g., priority application PCT/EP96/04810.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:00 A.M. to 5:30 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Cecilia Tsang can be reached at (571) 272-0562. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.



Jeffrey E. Russel  
Primary Patent Examiner  
Art Unit 1654

JRussel  
August 28, 2006